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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,776	08/18/2003	Swapan Roy	406-01	3684
39065	7590	10/11/2006	EXAMINER	
PROTEUS PATENT PRACTICE LLC			GROSS, CHRISTOPHER M	
P.O. BOX 1867			ART UNIT	
NEW HAVEN, CT 06508			PAPER NUMBER	

1639

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/642,776

Applicant(s)

ROY ET AL.

Examiner

Christopher M. Gross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-36 are pending

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to specificity determining substrate, classifiable in class 422, subclass 170.
- II. Claims 10-18, drawn to a protein-substrate complex, classifiable in class 435, subclass 174.
- III. Claims 19-24, drawn to a microarray, classifiable in class 435, subclass DIG 40.
- IV. Claim 25-36, drawn to a method of adsorbing a protein from a fluid, classifiable in class 436, subclass 161.

The inventions are distinct, each from the other because of the following reasons:

Each of inventions I, II, III versus invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of adsorbing a protein from a fluid can be performed using ordinary affinity chromatography media, rather than utilizing the substrate of invention I or the protein bound to said substrate per invention II or the microarray set forth in invention III.

Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs (structures) in that the substrate of invention I lacks the protein set forth in invention II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and III are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation in that the microarray set forth as invention III entail fluorescence measurements, etc which are not necessary in operating the substrate-protein complex of invention II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and III are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

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inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different modes of operation in that the microarray set forth as invention III entails fluorescence measurements, etc, which are not necessary in operating the substrate of invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Because each of these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because each of these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

### ***Species Election***

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Each genus identified below is indicated in **bold**. Applicant is requested to elect one species from within *each* genus of the elected invention. This application contains claims directed to the following patentably distinct species:

#### Elections for Group I:

(From claims 2 and 3) **specificity-determining ligand**: Applicant is required to elect a *single* particular structure, specified as to atom and bond. Applicant is strongly encouraged to elect using a structural representation. Currently, claims 1,2 and 3 are generic.

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The species are independent or distinct because they do not share a common structural core.

(From claim 4) **spacer**: Applicant is required to elect a *single* particular structure, specified as to atom and bond from which the search will commence. Applicant is strongly encouraged to elect using a structural representation. Currently, claims 1 and 4 are generic.

(From claim 5) **support**: selected from the group consisting of a glass surface, a silica surface, a ceramic surface, a plastic surface, a resin particle, a bead, a gel, a polyelectrolyte, and a hydrogel. Currently, claims 1 and 5 are generic.

The species are independent or distinct because they do not share a common structural core.

Elections for Group II:

(From claim 14) **support**: selected from the group consisting of a glass surface, a silica surface, a ceramic surface, a plastic surface, a resin particle, a bead, a gel, a polyelectrolyte, and a hydrogel. Currently, claims 10 and 14 are generic.

The species are independent or distinct because they do not share a common structural core.

Elections for Group III:

(From claims 20-21) Applicant is required to elect a **1<sup>st</sup> vs. 2<sup>nd</sup> locus** which differs (claim 20) or is identical (claim 21) from which the search will commence. Currently, claims 20-21 are generic.

(From claims 22-24) **specificity-determining ligand**: Applicant is required to elect a *single* particular structure, specified as to atom and bond. Applicant is strongly encouraged to elect using a structural representation. Currently, claims 22-24 are generic.

The species are independent or distinct because they do not share a common structural core.

Elections for Group IV:

(From claims 27-28) **specificity-determining ligand**: Applicant is required to elect a *single* particular structure, specified as to atom and bond. Applicant is strongly encouraged to elect using a structural representation. Currently, claims 25,27-28 are generic.

The species are independent or distinct because they do not share a common structural core.

(From claim 29) **support**: selected from the group consisting of a glass surface, a silica surface, a ceramic surface, a plastic surface, a resin particle, a bead, a gel, a polyelectrolyte, and a hydrogel. Currently, claims 25 and 29 are generic.

The species are independent or distinct because they do not share a common structural core.

(From claim 32) **hydrogel**: Applicant is required to elect a *single* particular structure, specified as to atom and bond from which the search will commence. Applicant is strongly encouraged to elect using a structural representation. Currently, claims 25 and 32 are generic.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

cg

  
MARK SHIBUYA, PH.D.  
PATENT EXAMINER